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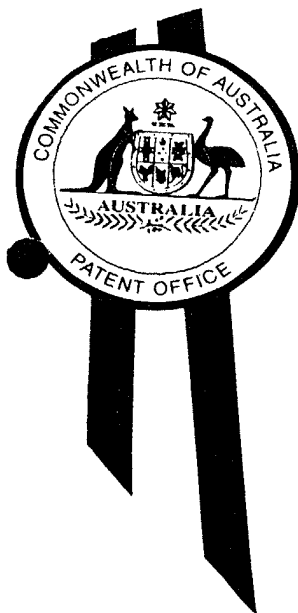
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I, LEANNE MYNOTT, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PQ2658 for a patent by GENETIC SOLUTIONS PTY LTD filed on 03 September 1999.



WITNESS my hand this  
Twentieth day of September 2000

LEANNE MYNOTT  
TEAM LEADER EXAMINATION  
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AUSTRALIA  
Patents Act 1990

PROVISIONAL SPECIFICATION

**Applicant:**

GENETIC SOLUTIONS PTY LTD  
A.C.N. 084 104 076

**Invention Title:**

SAMPLING SYSTEM

The invention is described in the following statement:

## SAMPLING SYSTEM

The present invention is concerned with a sampling system and, more particularly, with a sampling system for the storage of biological samples for subsequent analysis.

Biological samples are frequently collected in the field for later analysis for a variety of purposes. The analysis to be conducted will often be an analysis of the DNA contained in the sample in order to establish the genetic profile of the sample. Such an analysis may be conducted, for example, to verify and/or trace genetic lines in stock, to identify desirable traits in animals by identifying genetic markers for these traits or to identify the source of animal or plant material in a food product. For example, meat and meat products may be traced using DNA analysis in order to ensure that substitution of a lesser quality product has not occurred at any stage in the processing of the meat product or to identify the source of meat found to be contaminated in the marketplace.

DNA analysis for the purpose of identifying an individual organism is a well-known technique. For example, United States Patent No. 5,211,286, United States Patent No. 5,101,970 and United States Patent No. 5,856,102 describe systems for the identification of individual human beings in this way. In each case the invention is concerned with a personal identification system in which DNA-containing samples such as hair are stored in sealable plastic envelopes in a person's home to assist in their identification should the person become lost or go missing. However, each of these samples relies on the goodwill of those handling the DNA-containing materials prior to undertaking the analysis to ensure the integrity of the sample, since there is no means of avoiding tampering in the system or substitution of alternative samples. Accordingly, the only use for such systems is for an individual to store samples of their own DNA-containing

material where they have control of that sample, such as in the family freezer.

Attempts have been made to ensure that the identity of meat and meat products can be traced through the production process in a variety of ways. For example, the identity of beef, pigs and poultry on a batch or consignment basis is sometimes recorded using batch/consignment numbers applied to the batch/consignment source through the slaughter process to the consumer. Indeed, in some countries e.g. the United Kingdom, Government agencies issue numeric or alpha-numeric codes to farmers who subsequently allocate such codes to each of the animals bred by them. The allocated codes are generally inscribed on ear-tags applied to the animal and recorded on a card peculiar to the animal to allow for unique identification of that animal. Various other data on an animal may also be recorded, such as the vaccination records of the animal. The information can be forwarded to a Government agency progressively or at some time just prior to slaughter of the animal. Nevertheless, this system is administratively intensive and the identification and testing records are not easily integrated.

In the slaughter process a beast is often divided at an early stage, and then sub-codes identifying each half of the beast are generated and continue to be used to identify the halves. However, further division occurs later in the butchering process, at which point it becomes impractical to continue to assign codes to each batch of meat. Accordingly, although attempts have been made to continue to identify meat using tags or labels all the way through the process, it is difficult to ensure that such tags and labels are applied accurately. Therefore, the information provided in such systems may be inaccurate and the systems are highly labour intensive and expensive. Accordingly, meat and meat products will frequently be retailed without any identification tag or label able to trace the product through the slaughter process back to the

beast from which it originated.

International Application No. PCT/IE98/00021 describes a method for identifying the animal from which a meat product is derived, comprising genotyping the meat, comparing the genotype with known animal genotypes and locating any matching genotype to identify the animal from which the meat product is derived. The application of this method requires that DNA analysis be conducted of all animals and the data stored and then matched to any meat products tested. Alternatively, the samples from such beasts can be stored and then analysed later if the need arises. In either case, a library of genetic information of beasts is built up and compared to the DNA profile of meat analysed, either for routine quality assurance purposes (to trace product history to ensure, for example, that substitution of an inferior quality meat has not occurred) or, in instances where contamination of meat has been identified, so that the meat may be traced back to the trade source in an effort to identify the cause of the contamination.

The sampling system proposed in PCT/IE98/00021 is to take samples from animals in the conventional manner and then place them in an identification tube or cell which is marked with the animal tag identification code. The applicant asserts that "the identity of the cell remains constant through the method and system of the invention thereby guaranteeing the integrity and continuity of the tissue sample during extraction and analysis" but do not indicate just how this is achieved. Moreover, in describing the analysis they discuss a system whereby the labeled tube or cell is placed into a well of a microtitre plate having a multiplicity of such wells, with each well being provided with a code matching the animal tag identification code. The analysis is conducted in the marked microtitre plate but there is no way of ensuring, aside from matching the codes manually, that the correct identification tube or cell is placed in the correct well

in the microtitre plate. Thus, if only the code from the microtitre plate is used for subsequent identification, errors can occur. However, of still greater concern is the possibility that samples may be switched from one identification tube or cell to another long before such cells or tubes reach the laboratory where the analysis is conducted. Accordingly, if a person with fraudulent intent chooses to substitute one sample for another in the samples provided for DNA analysis, this substitution will not be detectable. The present invention seeks to provide a way of ensuring that the identity of a biological sample is known with certainty when an analysis of the sample is conducted.

According to a first aspect of the present invention, there is provided a device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis.

According to a second aspect of the present invention, there is provided a system for the analysis of a biological sample, comprising:

tamper-evident storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with the part of said storage means in which it is encased;

means for digesting said sample together with said part of said storage means; and

means for analysing said sample.

According to a third aspect of the present invention, there is provided a method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing

said sample, said storage means being adapted for digestion together with said biological sample for analysis; and storing said sample in said storage means.

According to a fourth aspect of the invention,  
5 there is provided a method of analysing a biological sample, comprising the steps of:

providing a device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being adapted for digestion  
10 together with said biological sample for analysis;

taking at least a portion of said sample together with the part of said storage means in which it is encased; digesting said sample together with said part of said storage means; and

15 analysing said sample.

The biological sample may be any suitable body part including animal hair, hide, buccal swabs, blood, muscle, bone, scales or the organs of an animal, or may be plant material such as leaves, stems or woody material.  
20 Body fluids including blood, saliva and urine may also be sampled.

Preferably the sample is subjected to analysis to establish a DNA profile, but the analysis may be for any material contained in said sample provided that it is  
25 present in sufficient quantities for the analysis and that none of the materials in said storage means interferes with the analysis. Typically, the analysis comprises amplification of the DNA contained in a sample such as animal hair using the polymerase chain reaction (PCR).

Typically, the sample is taken for analysis by  
30 punching out at least a portion of the sample that has been collected together with that part of said storage means in which it is encased, using a conventional punching device. It will be appreciated that contamination of the sample  
35 cannot occur in this process, as may occur, for example, if a sample is transferred from one vessel to another for analysis. Moreover, the integrity of the sample is ensured

since there is no possibility of accidental or deliberate switching of the sample at this stage.

The sample together with the part of said storage means is digested by conventional means for analysis. In  
5 the case of DNA for PCR analysis, this may be by a conventional alkali extraction or phenol/chloroform extraction. In this step, the material making up said storage means may dissolve or at least partially dissolve but should not interfere with development of the DNA  
10 profile.

In a particularly preferred embodiment of the invention, the device also bears a code corresponding to or linked to the animal tag identification code. This means that the sample from the animal is identified at the point  
15 of taking the sample by the same unique identifier or a different unique identifier provided the two are linked as the animal, and this unique identifier remains in physical juxtaposition with the biological sample from the time it is taken to the time the sample is analysed. Given that  
20 the storage means is tamper-evident, any tampering after collection, for example when a sample is archived, will be readily apparent to the person analysing the sample.

According to a fifth aspect of the present invention, there is provided a device for collecting and  
25 storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base  
30 sheet, said cover sheet being adapted for adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

35 Typically said base sheet is adapted for a biological sample to be positioned on a first surface and has printing identifying the sample on a second surface.



Typically the printing is a bar-code which encodes the animal tag identification code or the animal identification code itself. In the latter case, the code may be written into an appropriate space by the person taking the sample.

- 5 Typically, the second surface also includes information as to how to use the sample collection device.

The base sheet is typically a substantially rectangular sheet of paper, hence the first surface is the front of said base sheet and the second surface is its  
10 reverse. Preferably, the base sheet is a gloss art paper to ensure strong adhesion, and it should not contain any chemicals which will inhibit or interfere with the analysis to be conducted.

Each substantially rectangular base sheet may be  
15 joined by a line of weakness to a substantially identical sheet in order to connect a plurality of devices in accordance with the present invention. This allows the devices to be provided to the user as a roll from which individual sample storage devices may be torn off. The  
20 cover sheet may also be joined to adjacent cover sheets by a line of weakness, in which case separation of the cover sheet from the adjacent cover sheet is also necessary in order to remove an individual sample storage device. Alternatively, although it is not preferred, only the cover  
25 sheet may be connected to adjacent cover sheet by a line of weakness.

The base sheet and the cover sheet also include an elliptical bite taken therefrom which makes it easier for the backing sheet to be removed from the cover sheet,  
30 and is also useful in lining up rolls of individual sample storage devices during printing of the roll. The cover sheet may be hingedly secured to the base sheet in any convenient manner, but is typically secured thereto through adhesive securement along a line adjacent an edge of the  
35 base sheet. The adhesive securement may be along the entire length of said first edge or along a portion of said edge.

Typically, the cover sheet is coated across its entire surface with an adhesive and the backing sheet is applied to that portion of the cover sheet which is intended to encase the biological sample. The remainder of  
5 the cover sheet then adheres to the base sheet in order to hingedly secure it thereto.

The cover sheet is typically a polymeric film, preferably a clear polypropylene film.

The adhesive may be any suitable adhesive, and is  
10 typically a pressure-sensitive adhesive. It should contain no animal products so as not to introduce any foreign DNA into the analysis process.

The backing sheet is typically [PLEASE ADVISE]. In use, when the backing sheet is peeled from the cover  
15 sheet, the adhesive on the cover sheet bonds firmly and substantially irreversibly to said base sheet. Any efforts to peel the cover sheet from the base sheet would typically result in destruction of the base sheet and/or the cover sheet, or at least in sufficient mutilation of the two for  
20 the attempt to tamper with a sample to be apparent.

According to a sixth aspect of the present invention, there is provided a method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet  
25 having a cover sheet hingedly secured thereto, said cover sheet being adapted for adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

30 removing said backing sheet; and  
allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

Devices in accordance with the present invention  
35 may also be supplied together with a sampling device for sampling animal tissue.

Accordingly in a seventh aspect of the present

invention, there is provided a kit comprising a sample collection device as described above together with a sampling device.

5 The sampling device preferably takes a consistent and reproducible sample from animals whilst simultaneously avoiding any cross-contamination of tissue. Conventional sampling devices are envisaged.

Preferred embodiments of the present invention will now be described, by way of example only, with  
10 reference to the accompanying drawings, in which:

FIG. 1 is a bottom plan view of a device for storing a biological sample in accordance with the present invention;

15 FIG. 2 is a cross-section through a device for storing a biological sample in accordance with the present invention;

FIG. 3a is a flowchart illustrating the manner in which a device for storage of a biological sample in accordance with the present invention is prepared for use;

20 FIG. 3b is a flowchart illustrating the subsequent application of a biological sample to said device; and

FIG. 3c is a flowchart illustrating the manner in which a portion of said sample is taken for analysis.

25 A sample storage device 10 in accordance with the present invention, as best seen in FIG. 2 and the first frame of FIG. 3a, comprises a base sheet 11 arranged so that the biological sample may be positioned thereon, a cover sheet 12 hingedly secured to the base sheet 11 and  
30 having a backing sheet 13 releasably secured thereto. The base sheet 11 is printed on its reverse 14, which contains a bar-code 15 and also a space for writing an animal tag identification code where the sampler does not have facilities for reading a bar-code. In addition, the  
35 reverse 14 of the base sheet 11 contains instructions for use of the device, as will be discussed below in relation to FIG.s 3a-3c. The base sheet 11 is a sheet of 150 gsm A2

gloss art paper adapted to receive a biological sample on its obverse surface 17, as best seen in the first frame of FIG. 3b, where a biological sample 18 has been deposited thereon. It also adheres substantially irreversibly to the cover sheet 12 when the backing sheet 13 is removed therefrom and the two are brought together.

As best seen in FIG. 3a, the cover sheet 12 is hingedly secured to the base sheet 11. In fact, the surface 19 of the cover sheet 12 facing base sheet 11 is completely covered with adhesive and backing sheet 13 is releasably secured over a portion only of the cover sheet 12. It will be appreciated that backing sheet 13 is made of a release paper and so can be easily peeled off cover sheet 12, but the adhesive on cover sheet 12 bonds substantially irreversibly to base sheet 11. This means that the portion of the cover sheet 12 which is not covered by backing sheet 13 bonds strongly to base sheet 11. Accordingly, by leaving a region of cover sheet 12 uncovered by backing sheet 13, the cover sheet 12 can be hingedly secured to base sheet 11. In this case, the backing sheet 13 is substantially rectangular in shape and corresponds in size to the size of the cover sheet 12, which is also substantially rectangular in shape, except that the length of sides 20, 21 is slightly lesser than the sides 22, 23 of cover sheet 12. Hence a small portion of cover sheet 12 adjacent an edge is left exposed, and so adheres to base sheet 11 to form a hinged connection along line 24.

In use, a person taking a biological sample would read the instructions on the reverse 14 of the base sheet 11 and follow these. Accordingly, that person would be directed to peel back the backing sheet 13 in the manner shown in FIG. 3a and so expose the adhesive on cover sheet 12. This person would then place biological sample 18 centrally on the obverse surface 17 of base sheet 11 and allow the cover sheet 13 to collapse onto the biological sample 18 and base sheet 11 so as to adhere to them. This

is best seen in FIG. 3b. Having done this, the biological sample can be archived or sent immediately for analysis. At all times, the bar-code or animal tag identification code written on the back is in physical juxtaposition with the sample, which is encased in the sample storage device 10. If one were to attempt to remove the sample by peeling back cover sheet 13 from base sheet 11 damage to one or both sheets would occur, and the attempt to tamper with the integrity of the sample would be noted by a person subsequently conducting an analysis of the sample.

When analysis of the sample is to be conducted, a punch 25 is employed to punch a hole through the centre of biological sample 18 to create sub-sample 26. It will be appreciated that the punch removes the biological sample together with those portions of both the base sheet 11 and cover sheet 13 which encase it. The biological sample 18 does not need to be removed from the sample storage device 10 in any way prior to analysis, hence the possibility of cross-contamination is minimised and the opportunity for tampering with the sample or substitution with another sample is limited even at the analysis stage. The sub-sample 26 that is punched out will immediately be placed in an appropriate vessel for digestion and subsequent analysis in the conventional manner. The results of the analysis can then be matched to the animal tag identification code and/or bar-code to add to the information compiled on the beast from which the sample came. This allows for unequivocal identification of the genetic identity of the beast and so allows for comparison of DNA analysis of meat samples with these records to identify the source of any single piece of meat. In turn, this allows an audit line to be established to ensure that substitution of meat or meat products has not occurred and allows a source of contamination to be identified through tracing the contaminated meat back through the slaughter process to a particular beast.

EXAMPLE 1

A biological sample collected and stored in accordance with the present invention may then be subjected to PCR analysis to obtain a DNA profile using the following method:

Alkali Extraction Method

1. Take punch of sample from DNA Sample Collector, place in 0.2µl tube or well of 96 well microtitreplate.
2. Centrifuge tube/plate briefly to collect subsample into the bottom of the tube
3. Add 50µl of solution A [200mM NaOH].
4. Incubate at 95°C for 15 minutes. Mix the contents of the tube/plate 2-3 times during incubation by quickly removing the tube/plate from the heat block and tapping several times.
5. Briefly centrifuge to bring down any condensation on the lids of the tube/plate.
6. Add 50µl of solution B [200mM HCL, 100mM Tris.HCL, pH 8.5].
7. Mix briefly then centrifuge for 2 minutes at 13000rpm.
8. Transfer 80µl to a fresh tube/plate, avoiding the pellet of debris. Dilute with 100µl sterile MilliQ H<sup>2</sup>O.
9. Store at -20°C, use 1-2µl per PCR.

Throughout this specification and the claims, the words "comprise", "comprises" and "comprising" are used in a non-exclusive sense, except where the context requires otherwise.

Variations and modifications of this device will be apparent to the person skilled in the art, and those variations and modifications are within the scope of the present invention.

Dated this 3<sup>rd</sup> day of September 1999

GENETIC SOLUTIONS PTY LTD

By their Patent Attorneys

GRIFFITH HACK

5 Fellows Institute of Patent and  
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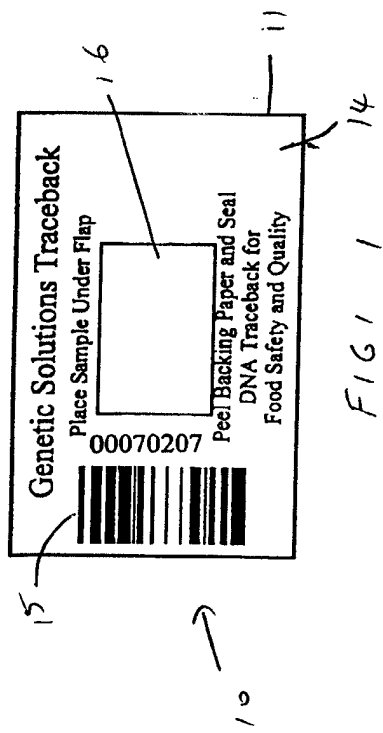


FIG 1

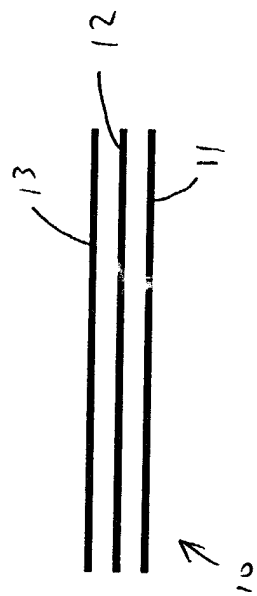


FIG 2

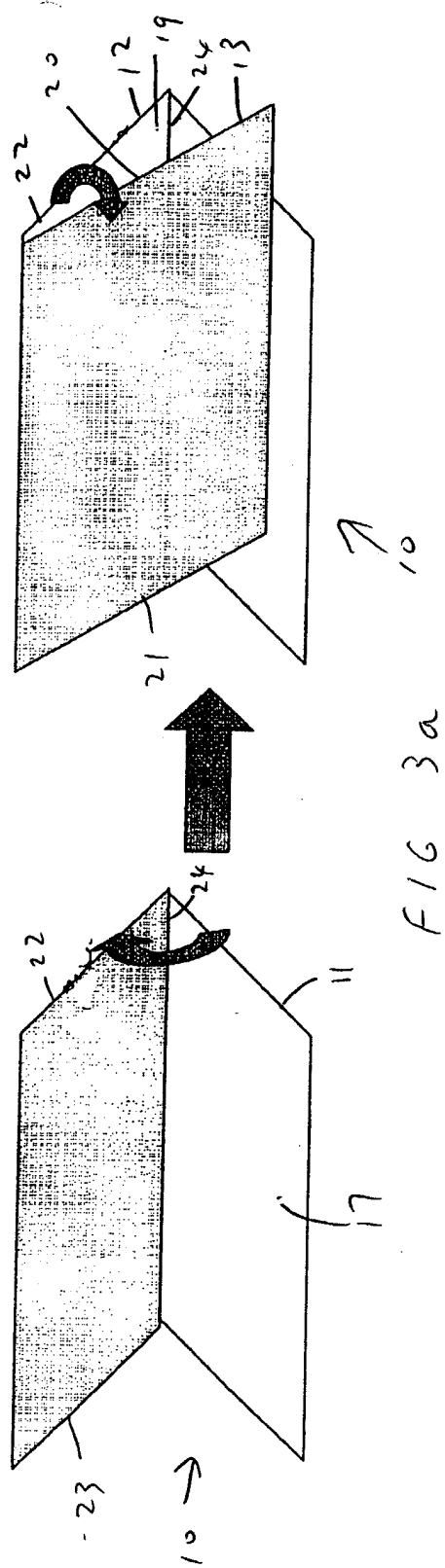
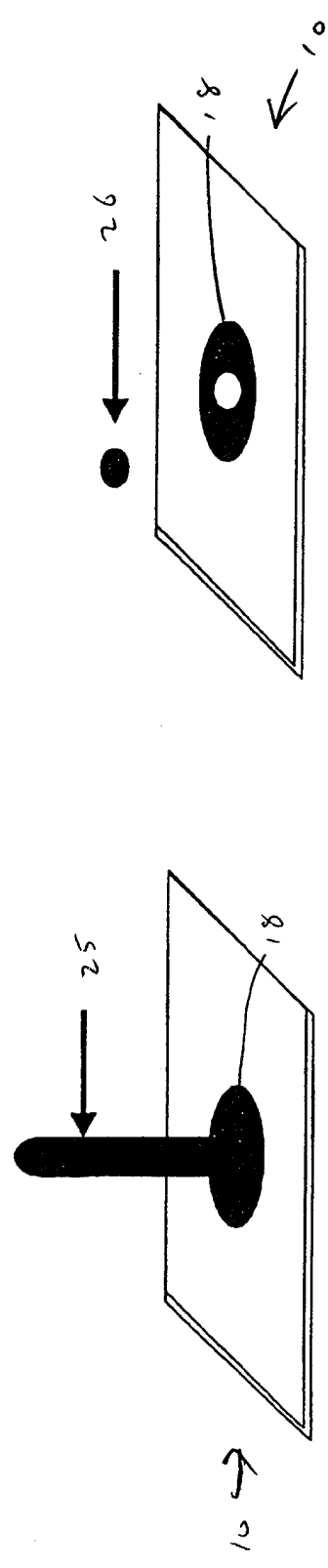
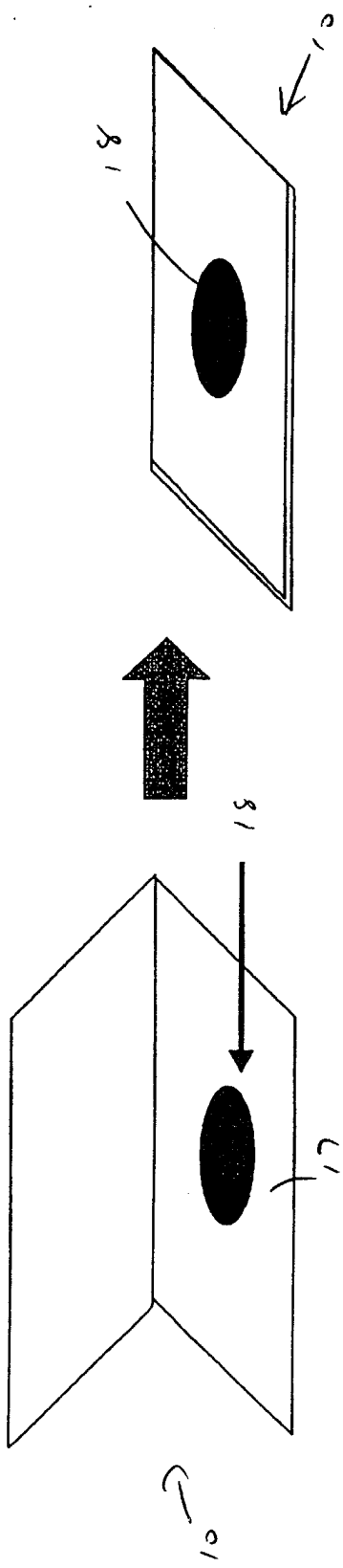


FIG 3a







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JC13 Rec'd PCT/PTO 10/069313  
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The Commissioner of Patents

30 July 2001

Madam

**IN THE MATTER OF International Patent Application No. PCT/AU00/01039  
in the name of GENETIC SOLUTIONS PTY LTD  
Entitled SAMPLING SYSTEM  
Our Ref: BJN:MAR:FPI3287**

We refer to the first Written Opinion of the International Preliminary Examining Authority in the above matter, and enclose a Statement of Amendments Under Article 34.

The Written Opinion rejected claims 1, 20-22, 28 and 36-37 as lacking novelty and inventive step over U.S. Patent No. 5,856,102, the D2 reference. The Written Opinion specifically cites col. 5, lines 28-39, of the D2 reference against the present application. This passage, however, does not teach or suggest the "sample collection device" now claimed in claims 1, 20-22, 28 and 36, because the passage refers to envelopes, which are not sample collection devices. D2 also sets forth that the envelopes are stored in "a home/self-storage setting such as a file drawer, safety deposit box, file cabinet, file drawer, etc." The home/self-storage settings in D2, however, are not "suitable for digestion", as found in claims 20-22. Finally, D2 does not teach or suggest the element "substantially irreversible adhesive securement" of a cover sheet to a base sheet, which is found in claims 1, 21, 28 and 36-37. "Substantially irreversible adhesive securement" is used so that "any tampering after collection, for example when a sample is archived, will be readily apparent to the person analyzing the sample." (See specification, page 7 line 36 to page 8 line 2). D2, which simply states that blood is applied to a card and then placed in an envelope, does not teach or suggest a device that will make any tampering with the sample readily apparent. Therefore, applicant respectfully request that the rejections be withdrawn for claims 1, 20-22, 28 and 36-37.

The Written Opinion rejected claims 1, 14, 21, 28 and 36-37 as lacking novelty and inventive step over U.S. Patent No. 3,965,888, the D4 reference. These rejections are improper because D4 does not teach or suggest the importance of the element "substantially irreversible adhesive securement" for a sample collection device used to collect and store a biological sample. For example, D4 simply suggests that an adhesive be used "to enable the taking of a specimen from the surface of a body." (col. 2, lines 37-40). Thus, the only purpose of the adhesive in D4 is to collect the specimen "by its sticking to the adhesive." (col. 3, lines 11-12). There is no suggestion or limitation that the adhesive is sufficiently strong to create substantially irreversible adhesive securement. Accordingly, applicant requests that the rejection over claims 1, 14, 21, 28, and 36-37 be withdrawn.

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- 2 -

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10/069313

JCI 1000000000 13 FEB 2002

The Commissioner of Patents (FP13287)


30 July 2001

The Written Opinion rejected claims 1, 7-14, 20-22, and 28-37 as lacking novelty and/or inventive step over Japanese Patent No. 11-166929 (D1) and Japanese Patent No. 10-267761 (D3). The abstract and figures 1-3 in each of the cited Japanese reference do not appear to teach or suggest at least any of the following elements found in these claims: "tamper-evident storage means;" "said storage means being suitable for digestion together with said biological sample;" or "substantially irreversible adhesive securement." Therefore, applicant respectfully requests that these rejections be withdrawn.

The Written Opinion also sets forth that WO 00/17396, although published later than the priority date of the current application, may "possibly be at least relevant in countries where both the applications are being simultaneously processed." Even if this reference were properly considered prior art in a country, WO 00/17396 does not teach or suggest many elements of the pending claims.

We look forward to receiving an International Preliminary Examination Report with positive statements concerning the novelty and inventiveness of the claimed invention.

Yours faithfully  
GRIFFITH HACK



Brendan Nugent

Encls.

# ARTICLE 34 AMENDMENTS – PCT/AU00/01039

## Description:

Replace pages 4, 5, 8, and 10 with new pages 4, 4/1, 5, 5/1, 8 and 10. The amendments are detailed below with added text underlined and deleted text placed within [] for ease of reference.

- The portion of the description originally featuring at page 4, lines 19 & 23 has been amended to read:

“invention, there is provided a sample collection device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means [being suitable for digestion together with said biological sample.] comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces; and

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;

wherein said storage means is suitable for digestion together with said biological sample.”

- The portion of the description originally featuring at page 4, line 27 has been amended to read:

“a sample collection device for collecting and storing a biological”

- The portion of the description originally featuring at page 5, lines 3 to 10 has been amended to read:

“invention there is provided a method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a sample collection device for collecting and storing a biological sample comprising tamper-evident storage means [being suitable for digestion together with said biological sample; and] for storing said sample, said storage means comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet

over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;

wherein said storage means is suitable for digestion together with said biological sample; and

storing said sample on a base sheet in said storage means."

- The portion of the description originally featuring at page 5, line 14 has been amended to read:

"providing a sample collection device for storing a biological"

- The portion of the description originally featuring at page 5, lines 25 to 37 has been deleted.

- The following portion of the description has been inserted at new page 5/1

"According to a fifth aspect of the invention there is provided a sample collection device for collecting and storing a biological sample for subsequent analysis, comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces; and

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

According to a sixth aspect of the present invention there is provided a method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

In particular, the cover sheet may be coated with a permanent adhesive across its entire surface, and the portion of the"

- The portion of the description originally featuring at page 8, lines 3 to 14 has been deleted.

- The portion of the description originally featuring at page 10, lines 9 to 21 has been deleted.
- The portion of the description originally featuring at page 10, lines 25 to 28 has been deleted.
- The portion of the description originally featuring at page 10, line 29 has been amended to read:  
"The sample collection device may be supplied as a part of a kit which further comprises a sampling device. The sampling device preferably takes a consistent"

Claims:

Replace claim pages 18 to 23 with new claim pages 18 to 23, having claims 1 to 32. Original claim pages with proposed amendments highlighted are also attached.

Abstract:

Replace abstract page 24.

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identification tube or cell is placed in the correct well in the microtitre plate. Thus, if only the code from the microtitre plate is used for subsequent identification, errors can occur. However, of still greater concern is  
5 the possibility that samples may be switched from one identification tube or cell to another long before such cells or tubes reach the laboratory where the analysis is conducted, since the tubes or cells are not secured. Accordingly, if a person with fraudulent intent chooses to  
10 substitute one sample for another in the samples provided for DNA analysis, this substitution will not be detectable. The present invention seeks to provide a way of ensuring that the identity of a biological sample is known with certainty when an analysis of the sample is  
15 conducted.

#### DISCLOSURE OF THE INVENTION

According to a first aspect of the present invention, there is provided a sample collection device  
20 for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means comprising:

a base sheet arranged so that the biological  
25 sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;  
30 and

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;  
wherein said storage means is suitable for digestion together with said biological sample.

35 According to a second aspect of the present invention, there is provided a system for the analysis of a biological sample, comprising:

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5 a sample collection device for collecting and  
storing a biological sample comprising tamper-evident  
storage means for storing said sample, said storage means  
being adapted for digestion together with said biological  
sample for analysis;

means for taking at least a portion of said  
sample for analysis together with at least the part of  
said storage means in which it is encased;

10 means for digesting said sample, or portion  
thereof, together with at least said part of said storage  
means; and



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means for analysing said sample.

According to a third aspect of the present invention, there is provided a method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a sample collection device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;

wherein said storage means is suitable for digestion together with said biological sample; and storing said sample on a base sheet in said storage means.

According to a fourth aspect of the invention, there is provided a method of analysing a biological sample, comprising the steps of:

providing a sample collection device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

digesting said sample, or portion thereof, together with at least said part of said storage means; and

analysing said sample.

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According to a fifth aspect of the invention there is provided a sample collection device for collecting and storing a biological sample for subsequent analysis, comprising:

5 a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over  
10 at least a substantial portion of their facing surfaces; and

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.

According to a sixth aspect of the present  
15 invention there is provided a method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible  
20 adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

removing said backing sheet; and

allowing said cover sheet to adhere substantially  
25 irreversibly to the base sheet and/or the biological sample positioned on said base sheet.

In particular, the cover sheet may be coated with a permanent adhesive across its entire surface, and the portion of the

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archived, will be readily apparent to the person analysing the sample.

Typically said base sheet is adapted for a biological sample to be positioned on a first surface and has printing identifying the sample on a second surface. Typically the printing is a bar-code which encodes the animal tag identification code or the animal identification code itself. In the latter case, the code may be written into an appropriate space by the person taking the sample. Typically, the second surface also includes information as to how to use the sample collection device.

The base sheet is typically a substantially rectangular sheet of paper, hence the first surface is the obverse of said base sheet and the second surface is its reverse. Preferably, the base sheet is a gloss art paper to ensure strong adhesion, and it should not contain any chemicals which will inhibit or interfere with the analysis to be conducted. Typically it is a sheet of 150gsm A2 gloss art paper

Each substantially rectangular base sheet may be joined by a line of weakness to a substantially identical sheet in order to connect a plurality of devices in accordance with the present invention. This allows the devices to be provided to the user as a roll from which

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the cover sheet, or at least in sufficient mutilation of the two for the attempt to tamper with a sample to be apparent.

5 An absorbent material may be secured on the front surface of said base sheet. This makes collection of body fluids easier as a quantity of these may be absorbed by the absorbent layer. Typically the absorbent layer is blotting paper.

10 Devices in accordance with the present invention may also be supplied together with a sampling device for sampling animal tissue.

The sample collection device may be supplied as a part of a kit which further comprises a sampling device. The sampling device preferably takes a consistent and  
15 reproducible sample from animals whilst simultaneously avoiding any cross-contamination of tissue. The nature of the sampling device will be well understood by the person skilled in the art, but is typically forceps or pliers. The kit may also include instructions for use of the  
20 sample collection device.

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CLAIMS

1. A sample collection device for collecting and storing a biological sample for subsequent analysis, comprising tamper-evident storage means for storing said sample, said storage means comprising:
- 5 a base sheet arranged so that the biological sample may be positioned thereon;
- a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over
- 10 at least a substantial portion of their facing surfaces; and
- a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;
- 15 wherein said storage means is suitable for digestion together with said biological sample.
2. A device as claimed in claim 1 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.
- 20
3. A device as claimed in claim 2 wherein the adhesive is a pressure-sensitive adhesive.
- 25
4. A device as claimed in any one of claims 1, 2 or 3 wherein print is on the reverse of said base sheet.
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5. A device as claimed in claim 4 wherein a bar code is printed on the reverse of said base sheet.
6. A device as claimed in any one of claims 1 or 2 to 5 wherein the base sheet is paper.
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7. A device as claimed in claim 6 wherein the base sheet is gloss art paper.

8. A device as claimed in any one of claims 1 or 2  
5 to 7 wherein the cover sheet is a clear polypropylene film.

9. A device as claimed in any one of claims of 1 or 2 to 8 wherein the backing sheet is a release paper.

10

10. A system for the analysis of a biological sample, comprising:

a sample collection device for collecting and storing a biological sample comprising tamper-evident  
15 storage means for storing said sample, said storage means being adapted for digestion together with said biological sample for analysis;

means for taking at least a portion of said sample for analysis together with at least the part of  
20 said storage means in which it is encased;

means for digesting said sample, or portion thereof, together with at least said part of said storage means; and

means for analysing said sample.

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11. A system as claimed in claim 10 wherein the device is a device as defined in any one of claims 1 or 2 to 9.

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12. A system as claimed in claim 10 or claim 11 wherein a hole punch takes a portion of said sample for analysis together with that part of the storage means in which it is encased.

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13. A system as claimed in any one of claims 10 to 12 wherein said sample is digested in an alkali extraction.

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14. A system as claimed in any one of claims 10 to 13 wherein said sample is subjected to amplification by PCR and then DNA sequencing.

5 15. A method of collecting and storing a biological sample for subsequent analysis, comprising the steps of:

providing a sample collection device for collecting and storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means comprising:

a base sheet arranged so that the biological sample may be positioned thereon;

a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces;

a backing sheet releasably secured to the surface of said cover sheet facing said base sheet;

wherein said storage means is suitable for digestion together with said biological sample; and storing said sample on a base sheet in said storage means.

16. A method as claimed in claim 15 wherein the device is a device as defined in any one of claims 1 or 2 to 9.

17. A method as claimed in claim 15 or claim 16 wherein said biological sample is stored for an extended period of time.

18. A method of analysing a biological sample, comprising the steps of:

providing a sample collection device for storing a biological sample comprising tamper-evident storage means for storing said sample, said storage means being suitable for digestion together with said biological sample;

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taking at least a portion of said sample together with at least the part of said storage means in which it is encased;

5        digesting said sample, or portion thereof, together with at least said part of said storage means; and

         analysing said sample.

19.        A method as claimed in claim 18 wherein the device is a device as defined in any one of claims 1 or 2  
10        to 9.

20.        A method as claimed in claim 18 or claim 19 wherein a portion of said sample is punched out of the sample collection device with a hole punch.  
15

21.        A method as claimed in any one of claims 18 to 20 wherein said sample is digested in an alkali extraction.

22.        A method according to any one of claims 18 to 21  
20        wherein said sample is subjected to amplification by PCR and then DNA sequencing.

23.        A sample collection device for collecting and storing a biological sample for subsequent analysis,  
25        comprising:

         a base sheet arranged so that the biological sample may be positioned thereon;

         a cover sheet hingedly secured to said base sheet, said cover sheet being adapted for substantially  
30        irreversible adhesive securement to said base sheet over at least a substantial portion of their facing surfaces; and

         a backing sheet releasably secured to the surface of said cover sheet facing said base sheet.  
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24.        A sample collection device as claimed in claim 23 wherein print is on the reverse of said base sheet.



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25. A sample collection device as claimed in claim 23 wherein a bar code is printed on the reverse of said base sheet.

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26. A sample collection device as claimed in any one of claims 23 to 25 wherein the base sheet is paper.

27. A sample collection device as claimed in claim 26  
10 wherein the base sheet is gloss art paper.

28. A sample collection device as claimed in any one of claims 23 to 27 wherein the cover sheet is coated with a permanent adhesive across its entire surface, and the  
15 portion of the cover sheet to which the backing sheet is not secured constitutes the hinged connection between the cover sheet and the base sheet.

29. A sample collection device as claimed in claim 28  
20 wherein the adhesive is a pressure-sensitive adhesive.

30. A sample collection device as claimed in any one of claims 23 to 29 wherein the cover sheet is a clear polypropylene film.

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31. A sample collection device as claimed in any one of claims of 23 to 30 wherein the backing sheet is a release paper.

30 32. A method of collecting and storing a biological sample, comprising the steps of:

applying said biological sample to a base sheet having a cover sheet hingedly secured thereto, said cover sheet being adapted for substantially irreversible  
35 adhesive securement to said base sheet over at least a substantial portion of their facing surfaces and bearing a backing sheet releasably secured thereto;

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removing said backing sheet; and  
allowing said cover sheet to adhere substantially  
irreversibly to the base sheet and/or the biological  
sample positioned on said base sheet.

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